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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,578	02/12/2004	Paul O. Sheppard	01-26C1	5427

7590 01/23/2007  
Robyn Adams  
Patent Department  
ZymoGenetics, Inc.  
1201 Eastlake Avenue East  
Seattle, WA 98102

EXAMINER
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HAYES, ROBERT CLINTON

ART UNIT	PAPER NUMBER
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1649

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/777,578

Applicant(s)

SHEPPARD ET AL.

Examiner

Robert C. Hayes, Ph.D.

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 3-6 and 8-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of Group I (claims 1-2 & 7) in the reply filed on 11/10/06 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 3-6 & 8-27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/10/06.

### *Claim Rejections - 35 USC § 101*

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-2 & 7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility.

Pages 1-2 of the specification disclose that "there remains a need in the art for further characterization of the human genome and the proteins encoded thereby. Previously unknown genes and proteins will be useful in the treatment and/or prevention of many human diseases, included diseases that have heretofore been refractory to treatment." The protein of SEQ ID NO: 2 is referred on pages 8-9 of the specification as one protein within "a group of *novel*, protein-encoding DNA molecules, designated 'MSP' proteins, polypeptides... [emphasis added]", and is

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a “secreted protein herein designated Zcyto27...”. Generic uses are further listed on pages 8-9 & 12-13, which include “used to direct the secretion of other [unknown] proteins of interest from a host cell”, and “can be fused to a different protein of interest to direct the protein through the secretory pathway of the cell”. Page 9 of the specification then asserts that “Zcyto27 bears significant identity to interleukin 2, interleukin 3, and interleukin 5, at [merely] 12, 13, and 12% respectively”. However, the specification discloses that “[t]ype 1 cytokines include IL-2... and are involved in inflammatory responses”, while [t]ype 2 cytokines include...IL-5... and are involved in humoral responses, helminth immunity and allergic response[s]”. In other words, because Zcyto27 shares equivalent “identity” to entirely different classes of cytokines, which possess their own unique activities, one skilled in the art could not reasonably extrapolate what activity Zcyto27 actually possesses, if later discovered.

In addition, a search of standard data bases indicates that Xcyto27 of SEQ ID NO: 2 alternatively shares a corresponding “significant identity” of 29.5% with human carboxypeptidases (i.e., U.S. Patent 6,441,153), and a 32.5% “significant identity” with an entirely different class of polypeptides, the ATPase component of the proline/glycine betaine ABC transporter system (Nolling et al, GenBank/EMBL Accession No. H97081). See attached sequence comparisons. Accordingly, Skolnick et al. (2000) teach in their review article that:

“Sequence-based methods for functional prediction are inadequate because of the multifunctional nature of proteins. Proteins can gain and lose function during evolution and may, indeed, have multiple functions in the cell (Box 1). Sequence-to-function methods cannot specifically identify these complexities. Inaccurate use of sequence-to-function methods has led to significant function-annotation errors in the sequence databases”. (e.g., see page 34).

Thus, in contrast to that asserted within the instant specification, one of skill in the art would not know what “use” the polypeptide of SEQ ID NO: 2 actually possesses, if any, until

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such is eventually discovered after-the-fact, because not a single specific and assayable function is disclosed for the polypeptide of SEQ ID NO: 2, and because not a single specific disease state that putatively can be treated by using this “novel” “secretory protein” is disclosed. Because many polypeptides may be useful to “direct the secretion of other [unknown] proteins of interest from a host cell”, because many different proteins may be useful in the treatment of unspecified diseases and disorders, and importantly, because the specific biological activity for even the specific Zcyto27 polypeptide depicted as SEQ ID NO: 2 is not known nor specifically described within the specification, one of ordinary skill in the art cannot reasonably extrapolate what constitutes a specific utility for the polypeptide of SEQ ID NO: 2.

Secondly, because no specific utility is described, or known, for the human Zcyto27 polypeptide of SEQ ID NO: 2, and because the specification merely and generically states that “MSP” proteins may be “useful in the treatment and/or prevention of many human diseases”, etc., which are further unknown and not disclosed at the time of filing Applicants’ invention, the instant invention also has no “substantial utility” because further experimentation is necessary at the time of filing the instant invention to attribute and discover a “real world” utility to the polypeptide of SEQ ID NO: 2. See MPEP 2107, and especially MPEP 2107.03.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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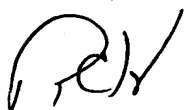
Claims 1-2 & 7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and/or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### *Conclusion*

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
January 17, 2007

ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER